P20757.A

Applicant : Yoshinobu HANYU et al.

Serial No. : 09/810,483

Filed : March 19, 2001

Group Art Unit: 1632

Examiner: Arun Chakrabarti, Ph.D

For : POWDER CONTAINING PHYSIOLOGICALLY ACTIVE PEPTIDE

AMENDMENT UNDER 37 C.F.R. § 1.111

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

Responsive to the Office Action of August 24, 2001, reconsideration and withdrawal of the rejections made therein are respectfully requested, in view of the following amendments and remarks. Inasmuch as the present Amendment is being submitted within the three-month shortened statutory period set in the Office Action to expire on November 26, 2001, November 24, 2001 falling on a Saturday, Applicant submits that no extension of time should be necessary. However, the Commissioner is authorized to charge any necessary fees to maintain the pendency of this application to deposit account No. 19-0089.

IN THE CLAIMS

Please cancel claims 25-32 without prejudice or disclaimer.

Please add new claims 33-54 as follows:

- - - 33. A powder containing a physiologically active peptide, wherein the powder comprises particles which particles comprise a physiologically active peptide and mannitol in a

weight proportion of from 1:1 to 1:50, the particles further comprising per one part by weight of the physiologically active peptide at least one of a nonionic surfactant in an amount of 0.05-3 parts by weight, a nonionic, organic, water-soluble binder in an amount of 0.05-6 parts by weight, and hydrogenated lecithin.

34. A powder containing a physiologically active peptide, wherein the powder comprises particles which particles comprise a physiologically active peptide and mannitol in a weight proportion of from 1:1 to 1:50, the particles further comprising per one part by weight of the physiologically active peptide a nonionic surfactant in an amount of from 0.05 to 3 parts by weight.

B1 cont

35. A powder containing a physiologically active peptide, wherein the powder comprises particles which particles comprise a physiologically active peptide and mannitol in a weight proportion of from 1:1 to 1:50, the particles further comprising per one part by weight of the physiologically active peptide a nonionic, organic, water-soluble binder in an amount of from 0.05 to 6 parts by weight.

36. A powder containing a physiologically active peptide, wherein the powder comprises particles which particles comprise a physiologically active peptide and mannitol in a weight proportion of from 1:1 to 1:50, the particles further comprising hydrogenated lecithin.

37. The powder of claim 33 wherein the average size of the particles is from 1 to 10 μm.

38. The powder of claim 34 wherein the average size of the particles is from 1 to 10 μm.

39. The powder of claim 35 wherein the average size of the particles is from 1 to 10 μm.

40. The powder of claim 36 wherein the average size of the particles is from 1 to 10 μm.

B1 cont

41. The powder of claim 33 prepared by spray drying, spray-freeze drying, or lyophilization.

42. The powder of claim 37 prepared by spray drying, spray-freeze drying, or lyophilization.

43. The powder of claim 33, wherein the physiologically active peptide comprises growth hormones, insulins, calcitonins, erythropoietin, glucagon, somatostatin, somatostatin derivatives, interferons, interleukins, superoxide dismutase, urokinase, proteases, tumor necrosis factors, colony-stimulating factors, kallikrein, lysozyme, fibronectin, insulin-like growth factors, epidermal growth factor, fibroblast growth factors, platelet-derived growth factor, nerve growth factor, hepatocyte growth factor, vasculogenesis factors or anti-vasculogenesis factors.

44. The powder of claim 37, wherein the physiologically active peptide comprises growth hormones, insulins, calcitonins, erythropoietin, glucagon, somatostatin, somatostatin derivatives,

interferons, interleukins, superoxide dismutase, urokinase, proteases, tumor necrosis factors, colony-stimulating factors, kallikrein, lysozyme, fibronectin, insulin-like growth factors, epidermal growth factor, fibroblast growth factors, platelet-derived growth factor, nerve growth factor, hepatocyte growth factor, vasculogenesis factors or anti-vasculogenesis factors.

45. The powder of claim 41, wherein the physiologically active peptide comprises growth hormones, insulins, calcitonins, erythropoietin, glucagon, somatostatin, somatostatin derivatives, interferons, interleukins, superoxide dismutase, urokinase, proteases, tumor necrosis factors, colony-stimulating factors, kallikrein, lysozyme, fibronectin, insulin-like growth factors, epidermal growth factor, fibroblast growth factors, platelet-derived growth factor, nerve growth factor, hepatocyte growth factor, vasculogenesis factors or anti-vasculogenesis factors.

46. The powder of claim 33, wherein the physiologically active peptide comprises human insulin.

47. The powder of claim 37, wherein the physiologically active peptide comprises human insulin.

48. The powder of claim 41, wherein the physiologically active peptide comprises human insulin.

49. The powder of claim 33, wherein the physiologically active peptide comprises human growth hormone.

50. The powder of claim 37, wherein the physiologically active peptide comprises human growth hormone.

B1 cont

51. The powder of claim 41, wherein the physiologically active peptide comprises human growth hormone.

52. An inhalant composition comprising a physiologically active peptide, wherein the inhalant composition comprises particles of claim 33.

53. An inhalant composition comprising a physiologically active peptide, wherein the inhalant composition comprises particles of claim 37.

54. An inhalant composition comprising a physiologically active peptide, wherein the inhalant composition comprises particles of claim 49. - - -

REMARKS

Reconsideration and withdrawal of the rejection in the outstanding Office Action are respectfully requested in view of the foregoing amendments and the following remarks.

Preliminary Matters

Initially, Applicants thank the Examiner for returning a duly initialed copy of the Form PTO-1449 with the Office Action, indicating consideration of the documents cited in the Information Disclosure Statement filed June 19, 2001.

Applicants note that the Examiner has not acknowledged receipt of the claim of priority and the priority documents in the Office Action. Applicant's request that the Examiner acknowledge receipt thereof and Applicants' claim of priority in the next communication from the Patent and Trademark Office.

Summary of Rejections

Claims 26 and 29 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The term "organic binder" in claim 26 is said to be not clear as to the meaning. The term "superoxide" in claim 29 is unclear.

Claims 25-26, and 28-31 are rejected under 35 U.S.C. § 102(b) as being anticipated by Samaritani (PCT International Publication No: WO 95/35116).

Claims 25-32 are rejected under 35 U.S.C. § 130(a) over Samaritani in view of Shigehara et al., U.S. Patent No. 5,763,439.

Summary of Amendment and Status of the Claims

Claims 25-32 were pending in the application upon issuance of the Office Action. Claims 25-32 are presently canceled without prejudice or disclaimer and replaced with new claims 33-54.

Independent claims 33-36 correspond to canceled claim 25 and include the features of canceled claim 26.

Claims 37, 38, 39 and 40 depend from claims 33, 34, 35 and 36, respectively, and correspond to canceled claim 27.

Claim 41 depends from claim 33 and corresponds to canceled claim 28.

Claim 42 depends from claim 37 and corresponds to canceled claim 28.

Claim 43 depends from claim 33 and corresponds to canceled claim 29.

Claim 44 depends from claim 37 and corresponds to canceled claim 29.

Claim 45 depends from claim 41 and corresponds to canceled claim 29.

Claim 46 depends from claim 33 and corresponds to canceled claim 30.

Claim 47 depends from claim 37 and corresponds to canceled claim 30.

Claim 48 depends from claim 41 and corresponds to canceled claim 30.

Claim 49 depends from claim 33 and corresponds to canceled claim 31.

Claim 50 depends from claim 37 and corresponds to canceled claim 31.

Claim 51 depends from claim 41 and corresponds to canceled claim 31.

Claim 52 depends from claim 33 and corresponds to canceled claim 32.

Claim 53 depends from claim 37 and corresponds to canceled claim 32.

Claim 54 depends from claim 49 and corresponds to canceled claim 32.

None of the new claims is drawn to the non-elected invention; however, Applicants expressly reserve the right to pursue the non-elected invention in a divisional application.

Response to § 112, ¶ 2 Rejections

Applicant respectfully submits that the § 112 rejections are moot in view of the cancellation and rewriting of the claims. Specifically, in the new claims, the binder is redefined as "nonionic, organic, water soluble" making even clearer that it is the binder which contains these characteristics. Further, the improper term "superoxide" resulted from a misplaced comma between superoxide and dismutase which has been corrected in the current claim language. In view of the new claims, which are believed to more definitely recite the claimed invention, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second Paragraph.

Response to § 102(b) Rejection

The rejection under 35 U.S.C. § 102(b) is respectfully traversed. Contrary to the statements in the Office Action, Samaritani discloses a solid mixture of hGH and mannitol. It also teaches the use of saccharose and glycine with hGH. Although they are well known diluents, saccharose and glycine are not "binders," because binders are compounds that impart cohesion to the body to be formed. As shown in the specification, lines 20-25, p. 4, polyvinylpyrrolidone, a water-soluble, nonionic, cellulose derivative (e.g. hydroxypropylcellulose, hydroxyethylellulose, and hydroxymethylcellulose) and polyvinyl alcohol are exemplary water-soluble, nonionic, organic binders. Unlike saccharose or glycine, it is characteristic of all these macromolecules to act as a glue to bind together. Therefore, Samaritani does not anticipate the compositions of any of claims 33-54, which, along with an

active peptide and mannitol, contain a nonionic surfactant, a nonionic, organic, water-soluble binder, or hydrogenated lecithin. As the Examiner is aware, anticipation under 35 U.S.C.§ 102(b) requires the disclosure in a primary prior art document of each and every element of the claims of the invention. In view of this failure to disclose all of the elements of the claims in a single document, Applicants respectfully request reconsideration and withdrawal of the rejection.

Response to § 103(a) Rejection

The rejection under 35 U.S.C. § 103(a) is respectfully traversed. Contrary to the statements in the Office Action, Shigehara is directed to a pharmaceutical composition containing a pyridazinone derivative. Shigehara merely states at col. 7, lines 59-66 that an "inhalant may be formulated by dissolving the compound of the present invention ... or may be administered to the respiratory airway in the form of a fine powder." Shigehara then further comments in a general manner in col. 8, lines 1-5 that "[s]uch an inhalant may be used, if necessary, in combination with other antiasthmatic agent or bronchodilator, such as Salbutamol, Ephedrin, Theophyline, Corticosteroid or ACTH."

It is clear that in these passages, Shigehara simply teaches the use of his pyridazinone derivative inhalant "in combination with" one of the other such agents. Shigehara does not teach the use of a powder which contains only peptides and inert ingredients, much less an inhalant. In particular, his reference to ACTH, a peptide, in the passage does not indicate explicitly or implicitly the use of an inhalant "containing ACTH," for inhalation is not a common way of

administration of a peptide. Shigehara does not provide any reference to administering a peptide by inhalation or a single example of an inhalant containing a peptide. Thus, the passage in Shigehara does not suggest any use of a powder containing a peptide.

Shigehara, therefore, does not motivate a person of ordinary skill in the art to combine its teachings with Samaritani for preparing an inhalable peptide composition. In view of Shigehara's failure to teach an inhalable peptide, and the lack of suggestion within Shigehara to combine its teachings with Samaritani, Applicants respectfully request reconsideration and withdrawal of the rejection.

Conclusion

For the foregoing reasons, it is believed that all of the claims in this application are in condition for allowance, which action is respectfully requested. In summary, Applicants have canceled the pending claims (claims 25-32) without prejudice or disclaimer, and replaced them with new claims 33-54 and have addressed the indefiniteness rejections, as discussed above. Applicants have also addressed the Examiner's art based rejections and pointed to the fallacies contained within them, as discussed above. Thus it is believed that all of the claims are in condition for allowance, which action is respectfully requested.

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If the Examiner has any questions, or wishes to discuss this matter, the Examiner is respectfully invited to contact the undersigned at the below-listed telephone number.

Respectfully submitted,
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